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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/564,075	02/20/2007	Jobst Krauskopf	19491	5999

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EXAMINER	
DAVIS, RUTH A	

ART UNIT	PAPER NUMBER
1651	

MAIL DATE	DELIVERY MODE
10/04/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/564,075	KRAUSKOPF ET AL.	
	Examiner	Art Unit	
	RUTH DAVIS	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 May 2011*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *1-14* is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *1-14* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

12)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/11*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's Request for Continued Examination, amendment, response and IDS filed May 16, 2011 have been received and entered into the case. Claims 1 – 14 are pending and have been considered on the merits. All arguments have been fully considered.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1 – 5, 7 – 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Reimer et al. (US 2003/0004095).

Reimer teaches a method for treating diabetes and secondary diseases thereof (abstract, 0002, 0008) comprising administering sweet whey permeate (0034, 0047), wherein glucose homeostatis (or glucose intolerance) (0009) and secondary diseases such as kidney failure or cardiovascular disorders or improved (0008). The whey is delactosed (or reduced in lactose) (0037), is orally administered as a powder, juice, or food (0057, example 8), or may contain pharmaceutically acceptable additives or carriers (example 5).

Although the reference does not specifically teach the whey permeate to have the claimed amounts of lactose, protein, fat and mineral substances, the permeates appear to be the same.

Thus the permeate of Reimer must inherently have the claimed amounts of each component.

Therefore, the reference anticipates the claimed subject matter.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1 – 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reimer (US 2003/0004095).

Reimer teaches a method for treating diabetes and secondary diseases thereof (abstract, 0002, 0008) comprising administering sweet whey permeate (0034, 0047), wherein glucose homeostatis (or glucose intolerance) (0009) and secondary diseases such as kidney failure or

cardiovascular disorders or improved (0008). The whey is delactosed (or reduced in lactose) (0037), is orally administered as a powder, juice, or food (0057, example 8), or may contain pharmaceutically acceptable additives or carriers (example 5).

Reimer does not specifically teach the composition wherein it is microencapsulated, wherein the patient is human, or wherein the permeate is hydrolyzed or partially hydrolyzed. However, the reference suggests administering the composition enterally (example 5). At the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to encapsulate an enteral composition as it was routine to do so in the art at the time of the claimed invention. Furthermore, while the reference does not expressly state the method is for humans, one in the art would understand that the reference suggests the method for treating humans. Finally, it is noted that the reference does teach protein hydrosylates (entire ref). Although the reference does not teach a hydrolyzed whey permeate, it would have been within the purview of one of ordinary skill in the art to use such a permeate in following the teachings of Reimer as it suggests hydrolyzed proteins for use in the methods of treating diabetes. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by the teachings of Reimer to use a hydrolyzed whey permeate in the methods of Reimer with a reasonable expectation for successfully treating diabetes.

Response to Arguments

Applicant argues that Reimer does not teach ultrafiltration of sweet whey permeate, the ranges of each component, or that the different constituents be present. Applicant additionally

argues that Reimer uses the product for different methods, is demineralized, that applicant claims a composition high in fat and that the reference does not teach administering to treat diabetes. Finally, applicant argues unexpected results, in that the composition prevents beta cell volume, reduces islets and that administering the composition has good results.

However, these arguments fail to persuade because the claims do not require that the permeate be anything other than a "whey permeate" that is sweet whey and reduced in lactose. The claims are not drawn to a product by process, they do not require the permeate to be made by a particular process that causes it to be structurally different from that of the prior art. It is noted that the claims merely require that the permeate have 74 – 94% lactose, with 0 - 14%, 0 - 10% and 0 - 17.5% of protein, fat and mineral substances, respectively. Moreover, the claims do not require protein, fat or mineral substances to be present in the permeate. Thus the argument is not commensurate in scope with the claims. It is additionally noted that the reference teaches a sweet whey permeate that has been processed by ultrafiltration (0047), which must inherently have produced a product as argued by applicant.

Regarding the intended use, Reimer teaches the composition for treating diabetes as claimed (abstract) therefore this argument is not persuasive. Regarding a demineralized permeate, it is noted that the prior art teaches that this is one of several ways the whey permeate may be processed (0037), however it is not required. The reference clearly teaches the whey permeate is obtained by well known methods in the art to include several methods to include those argued by applicant.

Regarding the unexpected results, applicant has failed to provide evidence of any unexpected result, benefit or activity of the instant composition or method. Since the prior art

teaches the same methods using the same sweet whey permeate, it is unclear what activity is unexpected.

For these reasons and those stated in the rejections above, the claims are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RUTH DAVIS whose telephone number is (571)272-0915. The examiner can normally be reached on M-F 7:00 -3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ruth A. Davis/
Primary Examiner, Art Unit 1651